

JAN 11 2001

K003396

9. 510(k) Summary

December 12, 2000

- I. Device Submitted: Water Jel's Burn Jel Plus
- II. Proprietary Name: Burn Jel Plus
- III. Common Name: Burn Jel Plus
- IV. Device Classification: Dressing, Wound and Burn, Hydrogel
- IV Submitted By: Water Jel Technologies ,243 Veterans Blvd, Carlstadt, NJ
07072 Tel: (201) 507-8300
- IV Contact Person: Michael Pisani
- V. Substantial Equivalence:

Burn Jel Plus, to be manufactured and distributed by Water Jel Technologies, is substantially equivalent to Burn Free Pain Relieving Gel manufactured for Nortrade Medical Inc, Burn Aid Gel manufactured by Rye Pharmaceuticals, Burn-Aid Hydrogel manufactured by MedTrak International and Burn Free manufactured by Levtrade International.
- VI. Device Description:

A First Aid water soluble, pain reliving gel packaged in a 3.5 g unit package and 4 oz bottle that cools, soothes, and moisturizes minor burns, scalds and sunburns.
- VII. Intended Use:

Burn Jel Plus is intended for First Aid Use on minor burns, scalds and sunburn, fast relief of minor burns, pre-medical first aid use for first and second degree burns and scalds, relieves pain, cools, soothes and moistens, bacteriostatic.
- VIII. Technological Characteristic Similarities:

Burn Jel Plus is a device similar in intended use and operative characteristics to Levtrade International's Burn Free, Rye Pharmaceuticals' Burn Aid Gel, MedTrak's Burn-Aid Hydrogel and Nortrade's Burn Free. Each device utilizes a water-soluble gel to provide cooling, soothing and moisturizing relief for minor burns including sunburns.
- VIII Biocompatibility Testing

Biocompatibility testing including the following: ISO Sensitization Study in the Guinea Pig, ISO Ocular Irritation Study in the Rabbit, Acute Oral Toxicity Screen in the Rat, ISO Skin Irritation Study in the Rabbit, and Cytotoxicity Study Using the Agarose Overlay Method were performed to demonstrate that Burn Jel Plus is biocompatible and safe for its intended use.
- IX Performance Data:

No performance standards applicable to this device have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act. A data base search has been performed to evaluate any adverse effects of like devices that are currently marketed.

10. Summary Of Safety And Effectiveness Database Search

Beginning with the year, 1966, to the present, a database search was completed for adverse safety and effectiveness reported with a topical gel used for pain relief associated with minor burns, scalds and sunburns. The database search did not produce any information regarding adverse effects from a topical gel used for treating minor burns, scalds and sunburns.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Mr. Michael Pisani
President
Water Jel Technologies
243 Veterans Boulevard
Carlstadt, New Jersey 07072

Re: K003396
Trade Name: Burn Jel Plus
Regulatory Class: Unclassified
Product Code: MGQ
Dated: October 31, 2000
Received: November 1, 2000

Dear Mr. Pisani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Michael Pisani

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003396

6. Indications For Use

Burn Jel Plus

The intended use of Water Jel's product, Burn Jel Plus, is for the following:

- First Aid Use on minor burns, scalds and sunburn,
- Fast relief of minor burns,
- Pre-medical first aid for first and second degree burns and scalds,
- To relieve pain,
- To cool, soothe and moisten, and
- Bacteriostasis.

Over-the-Counter Use ✓

Miriam C. Provost

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003396